

December 17, 2001

Marketing and  
Regulatory  
Programs

**CENTER FOR VETERINARY BIOLOGICS NOTICE NO. 01-16**

Animal and Plant  
Health Inspection  
Service

**Subject:** Autogenous Products for Avian Influenza

Veterinary Services

**To:** Biologics Licensees, Permittees, and Applicants  
Directors, Center for Veterinary Biologics  
Veterinary Services Management Team  
Area Veterinarians in Charge, VS  
State Veterinarians

Center for Veterinary  
Biologics  
Suite 104  
510 South 17th Street  
Ames, IA 50010  
(515) 232-5785  
FAX (515) 232-7120

The purpose of this notice is to remind interested parties that domestic distribution and use of avian influenza (AI) vaccines for any species may only be done under the supervision and control of USDA, APHIS, Veterinary Services (VS).

Requirements for the licensure of AI vaccines and a summary of the restrictions on their use are provided in Veterinary Services Memorandum No. 800.85, dated July 23, 1999. Avian influenza is considered a program disease by APHIS, VS, and any importation or interstate movement of AI viruses is strictly regulated and is only authorized by permit in accordance with 9 CFR 122.2.

The practice of producing AI vaccines as autogenous products under a firm's existing autogenous product license without specific authorization from APHIS, VS, does not meet these requirements and is prohibited. The Center for Veterinary Biologics (CVB) will not release autogenous AI vaccines without authorization from both the relevant State authorities, responsible officials of APHIS, VS, and if necessary, required permits for interstate transport.

/s/ Steven A. Karli

Steven A. Karli  
Director  
Center for Veterinary Biologics